PATENT COOPERATION TREATY

	From the INTERNATIONAL BUREAU		
PCT	То:		
NOTIFICATION OF ELECTION (PCT Rule 61.2)	United States Patent and Trademark Office (Box PCT) Washington D.C. 20231 United States of America		
Date of mailing:			
31 August 1995 (31.08.95)	in its capacity as elected Office		
International application No.: PCT/AU95/00086	Applicant's or agent's file reference: 66652		
International filing date: 23 February 1995 (23.02.95)	Priority date: 25 February 1994 (25.02.94)		
Applicant: ANDERSON, Sandra, Doreen			
1. The designated Office is hereby notified of its election made X in the demand filed with the International preliminary 08 August 1995	Examining Authority on: 5 (08.08.95) ational Bureau on:		

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland

Authorized officer:

J. Zahra

Telephone No.: (41-22) 730.91.11

Facsimile No.: (41-22) 740.14.35

PATENT COOPERATION TREATY

ì.	From the INTERNATIONAL BUREAU
PCT	To:

NOTIFICATION CONCERNING DOCUMENT TRANSMITTED

United States Patent and Trademark Office (Box PCT) Washington D.C. 20231 United States of America

Date of mailing (day/month/year)

08 December 1995 (08.12.95)

in its capacity as elected Office

International application No.

PCT/AU95/00086

International filing date (day/month/year) 23 February 1995 (23.02.95)

Applicant

CENTRAL SYDNEY AREA HEALTH SERVICE et al

> The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland

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23

PATENT COOPERATION TREATY

PC₁

PTO'D 08 DEC 1995

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 66652	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).			
International application No.	International filing dat	ing date Priority Date			
PCT/AU 95/00086	23 February 1995	10.4	25 February 1994		
International Patent Classification (IPC)	or national classification	on and IPC			
Int. Cl. ⁶ A61K 49/00 // 9/72, 33/14, 3	1/70				
Applicant (1) CENTRAL SYDNEY ARE (2) ANDERSON S.D.	EA HEALTH SERVI	CE	•		
1 This intermetional proliminary	evamination report has	heen prepared by the	nis International Preliminary Examining		
1. This international preliminary Authority and is transmitted to	the applicant according	g to Article 36.	is intermedian Frommany 2.mmms		
2. This REPORT consists of a tot	tal of 3 sheets, include	ding this cover sheet			
This report is also accombeen amended and are the (see Rule 70.16 and Sect	ne basis for this report a	nd/or sheets contain	scription, claims and/or drawings which have ing rectifications made before this Authority under the PCT).		
These annexes consist of a total	al of sheet(s).				
3. This report contains indications relati	ing to the following iter	ms:			
I X Basis of the repor	t				
II Priority					
III Non-establishmer	nt of opinion with regar	d to novelty, inventi	ve step and industrial applicability		
IV Lack of unity of it	nvention				
	ent under Article 35(2) lanations supporting such		ty, inventive step or industrial applicability;		
VI Certain document	ts cited		·		
VII Certain defects in	the international appli	cation			
VIII Certain observation	ons on the international	application			
Date of submission of the demand 8 August 1995		Date of completion of December 1995	f the report		
Name and mailing address of the IPEA	/AU · A	Authorized Officer			
AUSTRALIAN INDUSTRIAL PROPERTY	ORGANISATION				
PO BOX 200 WODEN ACT 2606	I	DOUGLAS THWAITES			
AUSTRALIA Facsimile No. (06) 285 3929 Telephone No. (06) 283 2265			283 2265		

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/AU 95/00086

I.	Basis of the report	
1.	This report has been drawn on response to an invitation under report since they do not contain	the basis of (Replacement sheets which have been furnished to the receiving Office in Article 14 are referred to in this report as "originally filed" and are not annexed to the n amendments.):
	the international	application as originally filed.
	X the description,	pages 1-21, as originally filed,
		pages , filed with the demand,
		pages , filed with the letter of ,
		pages , filed with the letter of .
	X the claims,	Nos. 1-21, as originally filed,
		Nos., as amended under Article 19,
		Nos., filed with the demand,
	•	Nos., filed with the letter of,
		Nos., filed with the letter of.
	X the drawings,	sheets/fig 1-4, as originally filed,
		sheets/fig , filed with the demand,
		sheets/fig , filed with the letter of ,
		sheets/fig , filed with the letter of .
2. Th	ne amendments have resulted in t	the cancellation of:
	the description,	pages
	X the claims,	Nos. 22-30
	the drawings,	sheets/fig
3.		ablished as if (some of) the amendments had not been made, since they have been considered sure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
4. Ac	ditional observations, if necessa	ry:
requ	se note that claims 1 to 21 are ire an international preliminary these claims have been examin	subject matters of rule 67.1 (method of treatments of humans) and as such do not y examination. However, because the subject matter does not contravene Australian ed.
	•	

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/AU 95/00086

V.	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement					
1.	Statement					
	Novelty (N)	Claims Claims	1-21		YES NO	
	Inventive step (IS)	Claims Claims	1-21		YES NO	
	Industrial applicability (IA)	Claims Claims	1-21		YES NO	

2. Citations and explanations

The present invention relates to dry powdered substances inhaled to provoke narrowing and mucociliary clearance of the airways. The substances achieve this effect by altering the osmolarity of the airway surface liquid. Examples of these substances include mineral salts, sugars and sugar alcohols.

Australian application AU 27462/92 discloses a liquid salt (NaCI) solution to be inhaled for treating asthma and allergies. Similar disclosures are made in Remington and DE 3518665. The use of salt solutions to treat asthma and allergies is known.

The present invention is directed towards a dry salt for provoking narrowing of the airways and for increasing mucociliary clearance. This appears to be a sufficient distinction from the prior art. The present invention is therefore regarded as novel and inventive.

INTERNATIONAL SEARCH REPORT



CLASSIFICATION OF SUBJECT MATTER

Int. Cl. 6 A61K 49/00 // 9/72, 33/14, 31/70

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

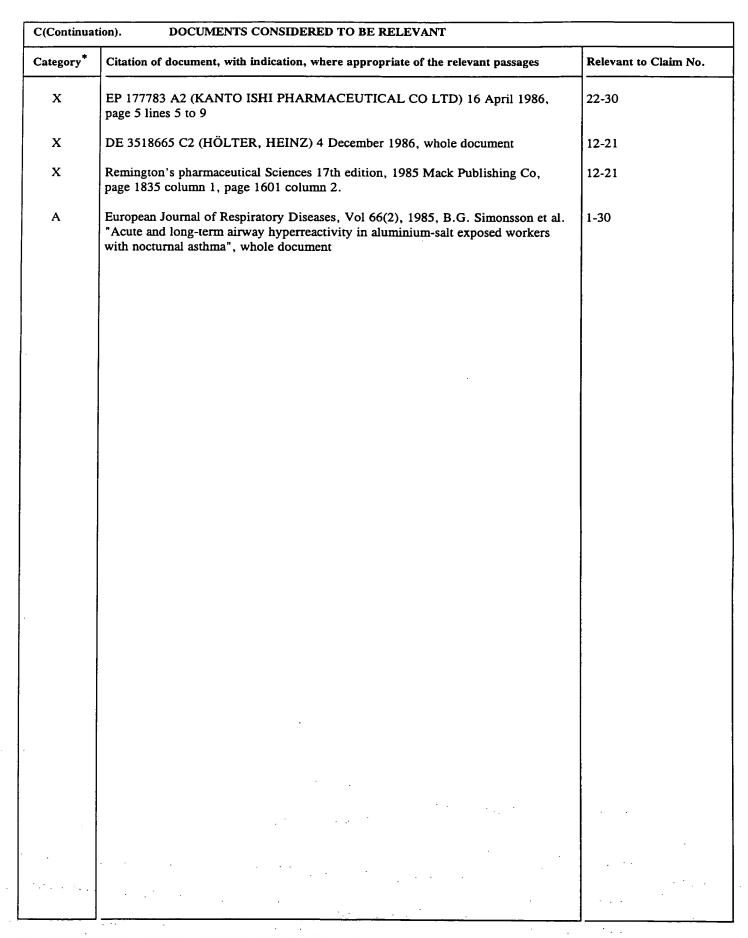
Minimum documentation searched (classification system followed by classification symbols) A61K 49/00 NaCl, Sodium()chloride, KCl, Potassium()chloride, Mannitol#, Sugar#, Salt#, Dextrose#, Powder#, Particle#, Dust#, Micron:, Particulate#, Inhale#, Inhalation, Breath, Respirable, Asthma:, Respirat:, Pulmon:, Lung#, Bronch:, Airway#

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base, and where practicable, search terms used)

DERWENT: WPAT, CASM C. DOCUMENTS CONSIDERED TO BE RELEVANT Category* Citation of document, with indication, where appropriate, of the relevant passages Relevant to Claim No. X AU 71645/87 A1 (CHIESI FARMACEUTICI S.P.A.) 11 September 1987. 22-30 page 2 line 9 to page 3 line 10, page 6 lines 9 to 15 AU 27462/92 A1 (KENNETH ROY HANSON) 6 May 1993, whole document X 12-21 AU 11648/92 A1 (GLAXO GROUP LTD) 6 August 1992, page 4 lines 7 to 9, X 22-30 claims 4 and 6 X AU 71559/91 A1 (NATIONAL RESEARCH DEVELOPMENT 22-30 CORPORATION) 8 August 1991, page 2 lines 28 to 30, page 7 lines 1 to 3, claims 3 and 20 X X Further documents are listed in the continuation of Box C. See patent family annex. Special categories of cited documents: later document published after the international filing date or priority date and not in conflict with the application but cited to understand the document defining the general state of the art which is not considered to be of particular relevance earlier document but published on or after the international filing date document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) document referring to an oral disclosure, use, exhibition or other means "A" principle of theory underlying the invention document of particular relevance; the claimed invention cannot be considered novel or cannot be "F" "X" "1" considered to involve an inventive step when the document is taken alone document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in "O" exhibition or other means document published prior to the international filing date but later than the priority date claimed "P" "&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report				
2 May 1995	13 JUNE 1995	(13.06.95)			
Name and mailing address of the ISA/AU	Authorized officer				
AUSTRALIAN INDUSTRIAL PROPERTY ORGANISATION PO BOX 200 WODEN ACT 2606					
AUSTRALIA	DOUGLAS THWAITES				
Facsimile No. 06 2853929	Telephone No. (06) 2832265				



This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

	Patent Document Cited in Search Report	Patent Family Member						
AU	A 94 62372	wo	9417822					
AU	A 87 71645	CA EP	1297012 258356	DE IT	3787502 1204826	EP	239798	
AU	A 92 27462		W			· · · · · · · · · · · · · · · · · · ·		
AU	A 92 11648	EP CA	496307 2112683	GB	9101592	wo	9212713	
AU	A 91 71559	CA GB	2049302 2240337	DE WO	69100792 9111179	EP	464171	
EP	177783	CA EP	1246452 429430	DE US	3587587 4698332	EP	177783	1 19 1 1 10

END OF ANNEX



INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 66652	FOR FURTHER ACTION		f Transmittal of International Preliminary ort (Form PCT/IPEA/416).	
International application No.	International filing da	ate	Priority Date	
PCT/AU 95/00086	23 February 1995		25 February 1994	
International Patent Classification (IPC) or national classificat	ion and IPC		
Int. Cl. ⁶ A61K 49/00 // 9/72, 33/14, 1				
Applicant (1) CENTRAL SYDNEY AR (2) ANDERSON S.D.	EA HEALTH SERV	TICE		
This international preliminary Authority and is transmitted t			nis International Preliminary Examining	
2. This REPORT consists of a to	otal of 3 sheets, inclu	uding this cover sheet	· -	
This report is also according been amended and are to (see Rule 70.16 and Sec	he basis for this report	and/or sheets contain	scription, claims and/or drawings which have ing rectifications made before this Authority under the PCT).	
These annexes consist of a tot	al of sheet(s).			
3. This report contains indications related	ting to the following ite	ems:		
I X Basis of the repo	rt ·			
II Priority				
III Non-establishme	nt of opinion with rega	rd to novelty, inventi	ve step and industrial applicability	
IV Lack of unity of	invention			
	ent under Article 35(2) lanations supporting su		ty, inventive step or industrial applicability;	
VI Certain documen	•			
VII Certain defects in	n the international appl	ication		
VIII Certain observati	ons on the internationa	al application	· ·	
		D		
Date of submission of the demand 8 August 1995 Date of completion of the report 1 December 1995			t the report	
Name and mailing address of the IPEA	/AU	Authorized Officer		
AUSTRALIAN INDUSTRIAL PROPERTY PO BOX 200				
WODEN ACT 2606 AUSTRALIA		DOUGLAS THWA	ITES	
AUSTRALIA Facsimile No. (06) 285 3929 Telephone No. (06) 283 2265				

1.	Basis of th	e report	,
re	esponse to		the basis of (Replacement sheets which have been furnished to the receiving Office in Article 14 are referred to in this report as "originally filed" and are not annexed to the namendments.):
		the international	application as originally filed.
	X	the description,	pages 1-21, as originally filed,
			pages, filed with the demand,
			pages , filed with the letter of ,
			pages , filed with the letter of .
	X	the claims,	Nos. 1-21, as originally filed,
			Nos. , as amended under Article 19,
			Nos., filed with the demand,
			Nos., filed with the letter of,
			Nos., filed with the letter of.
	X	the drawings,	sheets/fig 1-4, as originally filed,
			sheets/fig , filed with the demand,
			sheets/fig, filed with the letter of,
			sheets/fig , filed with the letter of .
2. The ar	nendments	s have resulted in th	ne cancellation of:
		the description,	pages
	X	the claims,	Nos. 22-30
		the drawings,	sheets/fig
3.			blished as if (some of) the amendments had not been made, since they have been considered are as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
4. Additi	onal obser	vations, if necessar	y:
Please n	ote that cl an internat	aims 1 to 21 are s	ubject matters of rule 67.1 (method of treatments of humans) and as such do not examination. However, because the subject matter does not contravene Australian



International application No.

PCT/AU 95/00086

v.	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;
	citations and explanations supporting such statement

1.	Statement			
	Novelty (N)	Claims 1-21 Claims	YES NO	
	Inventive step (IS)	Claims 1-21 Claims	YES NO	
	Industrial applicability (IA)	Claims 1-21 Claims	YES NO	

2. Citations and explanations

The present invention relates to dry powdered substances inhaled to provoke narrowing and mucociliary clearance of the airways. The substances achieve this effect by altering the osmolarity of the airway surface liquid. Examples of these substances include mineral salts, sugars and sugar alcohols.

Australian application AU 27462/92 discloses a liquid salt (NaCI) solution to be inhaled for treating asthma and allergies. Similar disclosures are made in Remington and DE 3518665. The use of salt solutions to treat asthma and allergies is known.

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INTERNATIONAL SEARCH REPORT

International application No. PCT/AU 95/00086

				-
	CLASSIFICATION OF SUBJECT MATTER 61K 49/00 // 9/72, 33/14, 31/70 of International Patent Classification (IPC) or to bot	h national classifica	tion and IPC	
B.	FIELDS SEARCHED	 		
A61K 49/0	ocumentation searched (classification system follow 0 NaCl, Sodium()chloride, KCl, Potassium()cust#, Micron:, Particulate#, Inhale#, Inhalati	chloride, Mannito	l#, Sugar#, Salt#, Dex	trose#, Powder#, rat:, Pulmon:, Lung#,
Documentati	on searched other than minimum documentation to	the extent that such	documents are included	in the fields searched
Electronic da	ata base consulted during the international search (in the WPAT, CASM	name of data base, a	and where practicable, se	arch terms used)
C.	DOCUMENTS CONSIDERED TO BE RELEV	ANT		
Category *	Citation of document, with indication, where	appropriate, of the	e relevant passages	Relevant to Claim No.
x	AU 71645/87 A1 (CHIESI FARMACEUT) page 2 line 9 to page 3 line 10, page 6 lines	22-30		
X	AU 27462/92 A1 (KENNETH ROY HANS	SON) 6 May 1993	, whole document	12-21
X	AU 11648/92 A1 (GLAXO GROUP LTD) claims 4 and 6	22-30		
X	AU 71559/91 A1 (NATIONAL RESEARC CORPORATION) 8 August 1991, page 2 li claims 3 and 20	22-30		
X Further in the	er documents are listed continuation of Box C.	X	See patent family anne	х.
* Specia	al categories of cited documents :	"T"	later document publish	ed after the international
"L" docum or whi	nent defining the general state of the art which is insidered to be of particular relevance document but published on or after the ational filing date the which may throw doubts on priority claim(s) is cited to establish the publication date of its cited to establish the publication date of its citation or other special reason (as specified)	"X" "Y"	principle of theory und document of particular invention cannot be co- considered to involve a document is taken alon document of particular	t cited to understand the lerlying the invention relevance; the claimed asidered novel or cannot be in inventive step when the e relevance; the claimed
"P" docum	nent referring to an oral disclosure, use, tion or other means tent published prior to the international filing date er than the priority date claimed	"&"	invention cannot be con inventive step when the with one or more other	e document is combined such documents, such ious to a person skilled in
	rual completion of the international search	Date of mailing of	f the international search	герог
2 May 1995		13 JUNE	1995 (13.0	6.95)
	ling address of the ISA/AU	Authorized officer	•	
AUSTRALIAI PO BOX 200 WODEN ACT AUSTRALIA	N INDUSTRIAL PROPERTY ORGANISATION I 2606	DOUGLAS TH	WAITES	
	i			

Telephone No. (06) 2832265

Facsimile No. 06 2853929



International application No. PCT/AU 95/00086

Category*	Citation of document, with indication, where appropriate of the relevant passages	Relevant to Claim No.		
x	EP 177783 A2 (KANTO ISHI PHARMACEUTICAL CO LTD) 16 April 1986, page 5 lines 5 to 9	22-30 12-21 12-21		
X	DE 3518665 C2 (HÖLTER, HEINZ) 4 December 1986, whole document			
X	Remington's pharmaceutical Sciences 17th edition, 1985 Mack Publishing Co, page 1835 column 1, page 1601 column 2.			
A	European Journal of Respiratory Diseases, Vol 66(2), 1985, B.G. Simonsson et al. "Acute and long-term airway hyperreactivity in aluminium-salt exposed workers with nocturnal asthma", whole document	1-30		
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INTERNATIONAL SEARCH REPORT Information on patent family member.

International application No. PCT/AU 95/00086

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

	Patent Document Cited in Search Report	Patent Family Member						
AU	A 94 62372	wo	9417822					
AU	A 87 71645	CA EP	1297012 258356	DE IT	3787502 1204826	EP	239798	
AU	A 92 27462		-		···			
AU	A 92 11648	EP CA	496307 2112683	GB	9101592	Wo	9212713	
ΑŪ	A 91 71559	CA GB	2049302 2240337	DE WO	69100792 9111179	EP	464171	-
EP	177783	CA EP	1246452 429430	DE US	3587587 4698332	EP	177783	-

END OF ANNEX